PCT/JP2003/010434

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E1-A0201P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/010434	International filing date (*day/month/year*) 19 August 2003 (19.08.2003)	Priority date (*day/month/year*) 22 August 2002 (22.08.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/09, C07K 14/46, C12N 5/10, C12Q 1/02, 1/68, G01N 33/15, 33/50, 33/53, 33/566		
Applicant EISAI CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18 December 2003 (18.12.2003)	01 July 2004 (01.07.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
PCT/JP2003/010434

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4, 8, 11, 12	YES
	Claims	1-3, 5-7, 9, 10	NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations

The following documents 1 and 2 are cited in the ISR.
Document 1: Adenomatous Polyposis Coli (APC) Protein Moves Along Microtubules and Concentrates at Their Growing Ends in Epithelial Cells, (Y. Minori-Kiyosue, et al.), J. Cell Biol., 7 February, 2000 (07.02.00), Vol. 148, No. 3, pages 505-518
Document 2: EB/RP Gene Family Encodes Tubulin Binding Proteins, (JP Juwana, et al.), Int. J. Cancer, 12 April, 1999 (12.04.99), Vol. 81, No. 2, pages 275-284, Abstract

Claims 1-3, 5-7, 9 and 10

The subject matters of claims 1-3, 5-7, 9 and 10 do not appear to be novel in view of document 1.

Document 1 describes a mutant APC protein without the 2159th position and subsequent amino acid domains at the C terminal, derived from a Xenopus, and a polynucleotide, etc. to code for the said protein, and describes that the said mutant APC protein is expressed in cells derived from a South African clawed frog by means of genetic engineering. The said mutant APC protein corresponds to mutant APC proteins described in claims 1-3.

Claims 1-12

The subject matters of claims 1-12 do not appear to involve an inventive step in view of documents 1 and 2.

Document 2 describes that mutation of APC gene is involved in polyps or cancer of the large intestine, that most of the said mutation cases are deficiencies of domains at the C terminal of APC protein, and that the domains at the C terminal of APC protein have a function of controlling cancer.

It is considered d that the multi-layering of cells described in claim 1 is a form observed characteristically in polyps or cancer.

Accordingly, a person skilled in the art could have easily created the subject matters of claims 1-12 by applying the genetic engineering techniques described in document 1 to the mutant APC described in document 2 that is deficient in C-terminal domains and does not have a function of inhibiting the development of polyps or cancer, in other words, the mutant APC to induce the multi-layering of cells.